

REMARKS

Reconsideration of this application and the rejection of claims 1-11 and 14-16 are respectfully requested. Applicant has attempted to address every objection and ground for rejection in the Office Action dated May 1, 2009 (Paper No. 20090430). Applicant believes the Application is now in condition for allowance or in better form for appeal. Additionally, as a follow-up to an August 25, 2009 telephone conference with the Examiner, Applicant intends to schedule an interview to further discuss this Application once an RCE is filed.

Claims 1-11 and 14-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,057,324 to Shibayama et al. ("Shibayama"). Shibayama is cited for teaching a rabbit skin abstract that has inhibitory activity against kallikrein formation. Applicant respectfully submits that the presently claimed subject matter differs substantially from Shibayama. Shibayama fails to teach, suggest, or disclose subject matter such as a rabbit skin having rabbit skin tissues possessing at least 0.5 iu/g SART activity. In both Amendment B and Amendment C, Applicant respectfully traversed the Examiner's contention that "regarding the SART activity, the skin of the art is the same as that claimed, thus it must intrinsically exhibit the claimed activity." In this instant Office Action, page 6, Examiner makes the same statement regarding the SART properties of the rabbit skin in Shibayama.

“If applicant adequately traverses the examiner’s assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also *Zurko*, 258 F.3d at 1386, 59 USPQ2d at 1697 (“[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings” to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2).” MPEP § 2144.04. In this case, the Examiner has failed to provide any evidence of Rabbit skin intrinsically possessing at least 0.5 iu/g SART activity. Applicant respectfully requests that documentary evidence be provided showing the rabbit skin of Shibayama intrinsically exhibits the claimed SART activity or that the rejection be withdrawn.

Furthermore, the claimed rabbit skin has both the Kallikrein production inhibition and SART activity. Conversely, the substances in Shibayama have the Kallikrein production inhibition, but no SART activity. In addition and as asserted by Examiner, the resultant rabbit skin in the present claimed invention is related to the process. In the description of the presently claimed invention, the elements of the process to prepare the rabbit skin are explained in detail. Shibayama describes a completely a different process that results in a completely different substance.

It is well known that the performance of a bio-product is decided by the constituent bio-active substances and that the bio-active substances are determined by a specific process. Such processes are typically complex because the reactions of animals to the stimulant (antigen) are often difficult to anticipate. Even with homozygous animals, the reactions are not homogeneous. For example, it is well known that a vaccine can be produced by inoculation with a virus. However, one of ordinary skill in the art cannot produce the vaccine only on this basis; many experiments are necessary that require choosing a suitable virus, preservation method and extraction method. Thus, the present technology is inherently unpredictable.

Moreover, Shibayama teaches using ultra-filtration to remove the substance with a molecular weight more than 20000 or less than 1000. However, the present invention only uses filtration under a nitrogen atmosphere which contributes to the claimed high SART activity. The process for creating the claimed substances also uses different virus types, administration methods and rabbit types than those taught or suggested in Shibayama. Again, the process taught in Shibayama is different than the process for obtaining the claimed rabbit skin. The differences in the processes results in two different substances.

The differences between Shibayama and the claimed invention can also be seen in the following table:

Production Process	Shibayama	Present Claimed Invention
raw material	Infected tissue of rabbit	Infected tissue of rabbit
reacting substance	Poxvirus(vaccinia virus)	Lister strain, Ikeda strain, Dairen strain and so on
extracting conditions	Not mentioned	filtration and concentration steps were carried out under nitrogen atmosphere
	The active charcoal was used at room temperature, and the eluting temperature of the absorbed extraction from the active charcoal is 60°C.	The active charcoal was used at 30°C, and the eluting temperature of the absorbed extraction from the active charcoal is room temperature.
	Ultrafiltration, the substance which molecular weight is more than 20000 and less than 1000 was removed	Filtration
	Not mentioned.	The extraction are heated at 121°C for 20min, the resultant substance is stable at 121°C.
resultant	A hygroscopic powder	The rabbit skin containing biologically active substances and the extracted solution
effect	Inhibitor of kallikrein formation	Kallikrein production inhibition and SART activity

Accordingly, the Section 102 rejection is respectfully traversed for these reasons.

Claims 1-11 and 14-16 also stand rejected under 35 U.S.C. §103, as being obvious in view of Shibayama. The arguments submitted above are reasserted here and the obviousness rejection of claims 1-11 and 14-16 is respectfully traversed.

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Response to Office Action mailed May 1, 2009

In view of the above-identified amendments and remarks, Applicant respectfully submits that the claims in their present form are allowable over the issues raised in the Office Action mailed May 1, 2009. In the event that there are further issues which may be resolved by a telephone interview, the Examiner is urged to contact Applicant's undersigned Attorney at the telephone number listed below.

Respectfully submitted,

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